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Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

2-Chloro-5-methoxybenzenesulfonamide
CAS#: 502187-53-3

This letter is to inform you of the results of a repeat dose toxicity study with the above referenced test substance.

Five groups of young adult male and female Crl:CD(SD) rats (5/sex/concentration) were administered diets that contained 0, 250, 800, 2500, or 7500 ppm for at least 15 days. Body weights, food consumption, and detailed clinical observations were evaluated weekly and acute clinical observations were evaluated daily in all animals. The animals were evaluated for clinical pathology (hematology, coagulation, clinical chemistry, urinalysis), organ weights, and gross and microscopic pathology at the end of the exposure period. Reductions (compared to control) in body weight and nutritional parameters in males and females at ≥ 2500 ppm, minimal to mild mucosal hyperplasia in the urinary bladder in males fed ≥ 2500 ppm, and evidence of anestrus in females fed 7500 ppm were noted in the study.

Sincerely,

Substantiation Questions

If the answer is no, please provide company name, address and telephone number of entity asserting claim.

The claim of confidentiality is requested permanently, or until the submitter makes the information common knowledge.

$$[$$

Disclosure of confidential information within the Company is on a need-to-know basis.

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a. Advertising or promotional material for the chemical substance or the resulting and product;

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[]. MSDSs or other similar materials for the substance disclose only a generic name for the test substance.

c. Professional or trade publications;

[]

d. Any other media or publications available to the public or to your competitors.

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If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.

Disclosure of the claimed CBI would result in harmful effects on submitter's competitive position since the submitter has committed, or expects to commit, a significant amount of time, resources, and dollars to the research and development of the test substance. Disclosure of the claimed CBI would permit a competitor to specifically know and understand the submitter's research efforts with this test substance and to forego the necessary time and expense to develop such a substance, thus capitalizing on the submitter's research and development efforts. This knowledge could be used by competitors to introduce new patents and/or competitive products in the areas of interest to our company which would otherwise reduce the value of this product for our business.

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

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10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?

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- a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?

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- b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

N/A.

c. What is the substance used for and what type of product(s) does it appear in.

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11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

It is anticipated that a competitor could readily reverse engineer this product, especially if CBI is revealed.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. Confidential processes used in manufacturing the substance;

No.

b. If a mixture, the actual portions of the substance in the mixture; or

No.

c. Information unrelated to the effects of the substance on human health or the environment?

Yes.

If your answer to any of the above questions is yes, explain how such information would be revealed.

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13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

The product (or test substance) does have a Chemical Abstract Service Registry Number (CAS RN 502187-53-3).

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

No.